REMARKS

Claims 1-6, 8, and 11-43 are pending in the application, wherein claims 7, 9 and 10 have been cancelled, claims 1-6, 8, 11-16, 21-23, 26, 29, 33, 35-39, and 41-43 have been amended, and claims 16-20 and 39-43 are currently withdrawn from consideration as being directed to non-elected inventions. In view of the amendments set forth above, Applicants respectfully request reconsideration and allowance of the above-identified application. In addition, Applicants believe that claims 16-20 and 39-43 are suitable for rejoinder upon the allowance of claim 1 since they recite the use of the sustained release composition of claim 1.

Each of independent claims 1, 21 and 33 was amended to specifically recite the inclusion of "powdered cellulose". Support for this limitation is found in originally filed claims 10, 35, and 41, as well as paragraph 22 of the written description. It is well-known to those of ordinary skill in the art that cellulose is largely insoluble in water. "Powdered cellulose" is likewise largely insoluble in water as indicated by the publicly available documents found using a Google search of the Internet attached at Exhibits "A" and "B". The insolubility of cellulose is what keeps trees, plants, wood and the like from dissolving when exposed to water.

Notwithstanding the fact that cellulose is largely insoluble in water, it may be chemically modified to yield cellulose derivatives (*e.g.*, cellulose ethers) that are soluble in water. An example of a water-soluble, chemically modified cellulose derivative is carboxymethylcellulose sodium, which is described in the publicly available document attached as Exhibit "C". Other examples of chemically modified cellulose derivatives include methylcellulose (MC), methylhydroxyethylcellulose (MHEC), methylhydroxypropylcellulose (MHPC), hydroxy-ethylcellulose (HEC), hydroxyethylcarboxymethylcellulose (HECMC), carboxymethylcellulose (CMC), and carboxymethylhydroxyethylcellulose (CMHEC), which are described in the first paragraph of the publicly available document attached as Exhibit "D" as being "water-soluble". Cellulose ethers are sometimes referred to as "film formers" and "film-forming polymers" because of their ability to dissolve in water and then form a film upon removal of the water by evaporation. *See* U.S. Patent No. 5,470,581 to Grillo et al., col. 2, lines 1-5; U.S. Patent No. 6,417,227 to Lord et al. In view of the foregoing, it is clear that the term "powdered cellulose" excludes cellulose ethers and other cellulose derivatives that are readily soluble in water.

None of the cited references teach or suggest "a sustained-release composition" comprising a mixture of "powdered cellulose" and maltodextrin within the claimed ratios in

order to slow the disintegration of an orally-administered specimen within which the sustained-release composition is dispersed in order to "provide a sustained release of [a] bioactive substance over a period of time of at least one hour" (claims 1 and 21), or so that a "released glucosamine-based substance does not significantly irritate a recipient's stomach lining" (claim 33). For example, Grillo teaches the use of a combination of maltodextrin and a "cellulosic polymer film former" (*e.g.*, one or more of "methylcellulose, hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose (HPMC), hydroxyethylcellulose, or carboxymethylcellulose") capable of dissolving in water. Grillo, col. 2, lines 1-5; Exhibit "D". Grillo neither teaches nor suggests the use of "powdered cellulose" within a sustained release composition. Moreover, Grillo neither teaches nor suggests a sustained release composition that is capable of being mixed throughout an orally administered specimen, but rather teaches a film-forming "coating" that is formed by dissolving the cellulose polymer film former and maltodextrin in water and then coating a tablet with the resulting coating mixture. *See* Col. 2, lines 1-5; col. 4, lines 26-37; col. 5, lines 63-67; col. 6, lines 32-35. In view of the foregoing, Grillo neither teaches nor suggests the compositions recited in the claims as now amended, either alone or in combination with any other art of record.

U.S. Patent No. 6,069,172 to Bertini et al. likewise fails to teach or suggest the use of a sustained release composition comprising "powdered cellulose" and maltodextrin in the claimed ratios in order to "provide a sustained release of [a] bioactive substance over a period of time of at least one hour" (claims 1 and 21) or so that a "released glucosamine-based substance does not significantly irritate a recipient's stomach lining" (claim 32). Instead, Bertini discloses the use of 10-80% of an "excipient" such as maltodextrin and 2-10% of a water-soluble "binding substance" "such as polyvinylpyrrolidone, alginates, carboxymethylcellulose sodium [or] carboxymethylcellulose starch". Because of this, comparing the concentration of the "excipient" (*i.e.*, 10-80%) to that of the binding substance (*i.e.*, 2-10%) is irrelevant to the claims in the above-identified application as now amended. Whereas Bertini discloses powdered cellulose as an example of an "excipient" component, including 10-80% powdered cellulose in combination with 2-10% of a water-soluble "binding substance" neither teaches nor suggests a sustained release composition comprising the combination of "powdered cellulose" and maltodextrin in the claimed ratios in order to provide the claimed sustained release benefits. In fact, because powdered cellulose and maltodextrin are both examples of the "excipient" of Bertini, there is no

teaching or suggestion in Bertini to specifically combine powdered cellulose with maltodextrin to yield a sustained release composition of any kind, let alone one having the specific concentration ratios and sustained release properties recited in the claims. That Bertini neither teaches nor suggests combining together powdered cellulose and maltodextrin is further evidenced by the examples set forth in Bertini, none of which contain powdered cellulose, maltodextrin, or a mixture thereof. Applicants therefore submit that Bertini neither teaches nor suggests the use of the claimed sustained release compositions as recited in the claims as amended, either alone or in combination with any other art of record.

Finally, neither U.S. Patent No. 5,128,143 to Baichwal et al. nor Lord teach or suggest the use of the claimed sustained release compositions as recited in the claims as now amended. Baichwal, like Grillo and Bertini, discloses the use of water-soluble cellulose ethers. Col. 6, lines 49-50. Baichwal neither teaches nor suggests combining "powdered cellulose" with maltodextrin in the claimed ratios to yield the claimed sustained release properties. Lord likewise discloses water-soluble "film-forming polymers" used to make "enteric coatings", including "chemically modified cellulose derivatives". Col. 8, lines 7-16. Lord neither teaches nor suggests a sustained release composition comprising "powdered cellulose" and maltodextrin in the claimed ratio to yield the claimed sustained release properties, as recited in the claims as now amended.

Finally, one of skill in the art would not have been motivated to combine any of the foregoing references with the document identified as "Green Processing Corporation" in the Office Action since "Green Processing Corporation" merely relates to the use of a specific form of maltodextrin called "Maltrin" "in consumer products as dry mixes". There is no teaching or suggestion in any of the references that the use of Maltrin having no protein, fat or fiber would yield the specific sustained release properties recited in the claims as now amended. More fundamentally, there is no teaching or suggestion in any of the references to specifically combine Maltrin with "powdered cellulose". Therefore, one of skill in the art would not have been motivated to combine the teachings of "Green Processing Corporation" with any of the cited references, nor would there have been a reasonable expectation of success if the aforementioned references were modified according to "Green Processing Corporation" to include Maltrin.

In view of the foregoing, Applicants submit that the claims as now amended are in allowable form. In the event that the Examiner finds any remaining impediment to a prompt

allowance of this application that may be clarified through a telephone interview, or that may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 6th day of January 2004.

Respectfully submitted,

JOHN M. GUYNN
Attorney for Applicants
Registration No. 36,153
Customer No. 022913

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JMG0000000551V001.DOC

POWDERED CELLULOSE

Prepared at the 20th JECFA (1976), published in FNS 1B (1977) and in FNP 52 (1992)

SYNONYMS INS No. 460(ii)

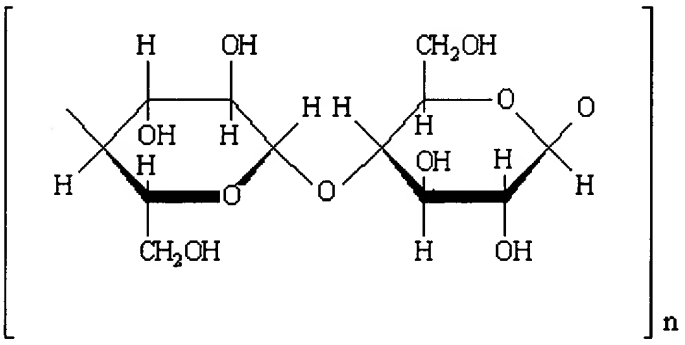
DEFINITION

Chemical names Cellulose, linear polymer of 1:4 linked glucose residues

C.A.S. number 9004-34-6

Chemical formula $(C_{12}H_{20}O_{10})_n$

Structural formula



Formula weight $(324)_n$ (n is predominantly 500 and greater)

Of the order of 1.6×10^5 and greater

Assay Not less than 92% $(C_{12}H_{20}O_{10})_n$

DESCRIPTION Purified, mechanically disintegrated cellulose prepared by processing alpha cellulose obtainted as a pulp from fibrous plant materials; occurs as a white, odourless substance consisting of fibrous particles which may be compressed into self-binding tablets which disintegrate rapidly in water; exists in various grades exhibiting degrees of fineness ranging from a dense free flowing powder to a coarse, fluffy non-flowing material.

FUNCTIONAL USES Anticaking agent, dispersing agent, texturizing agent

CHARACTERISTICS

IDENTIFICATION

Solubility Insoluble in water, ethanol, ether and dilute mineral acids. Slightly soluble in sodium hydroxide solution

Suspension formation Mix 30 g of the sample with 270 ml of water in a high-speed (12,000 rpm) power blender for 5 min. The resultant mixture will be either a free-flowing suspension or a heavy, lumpy suspension which flows poorly, if at all, settles only slightly and contains many trapped air bubbles. If a free flowing suspension is obtained, transfer 100 ml into a 100-ml graduated cylinder and allow to stand for 1 h. The solids settles and a supernatant liquid appears.

PURITY

Loss on drying Not more than 7% after drying (105°, 3 h)

pH 5.0 - 7.5

Mix 10 g of the dried sample, accurately weighed, with 90 ml water and allow to stand with occasional stirring for 1 h.

Water soluble substances Not more than 1.5%

Mix about 6 g of the sample, previously dried, with 90 ml of recently boiled and cooled water and allow to stand with occasional stirring for 10 min. Filter, discard the first 10 ml of

	filtrate and pass the filtrate through the same filter a second time if necessary to obtain a clear filtrate. Evaporate a 15 ml portion of the filtrate to dryness in a tared evaporation dish on a steam bath, dry at 105° for 1 h. Not more than 15 mg of residue is obtained.
Total ash	Not more than 0.3% (at approximately 800° to constant weight).
Starch	Not detectable
	To 20 ml of the mixture obtained in the Identification Test B add a few drops of iodine TS and mix. No purplish-to-blue or blue colour is produced.
Arsenic	Not more than 3 mg/kg (Method II)
Lead	Not more than 10 mg/kg
Heavy metals	Not more than 20 mg/kg
	Test 1 g of the sample as directed in the Limit Test (Method II)

Powdered Cellulose

Definition Powdered Cellulose is composed mainly of cellulose obtained by decomposing pulp.

Description Powdered Cellulose occurs as a white powder. It is odorless.

Identification (1) To 10 g of Powdered Cellulose, add 290 ml of water and mix in a high-speed (12,000 rpm or more) power blender for 5 minutes. Transfer 100 ml of the mixture to a 100-ml measuring cylinder and allow to stand for 1 hour. The suspension separates into a clear or white supernatant liquid and a precipitate.

(2) Dry Powdered Cellulose, and proceed as directed in the Potassium Bromide Disk Method under Infrared Spectrometry. The infrared absorption spectrum for the sample is observed at wavenumbers corresponding to the Reference Spectrum.

Purity (1) pH 5.0• 7.5.

Weigh accurately 10.0 g of Powdered Cellulose, add 90 ml of water, allow to stand while stirring occasionally for 1 hour, and centrifuge. Use the supernatant liquid for measurement.

(2) Water soluble substances Not more than 1.5%.

Weigh accurately about 6.0 g of Powdered Cellulose, previously dried, add 90 ml of water freshly boiled and cooled. Allow to stand for 10 minutes while stirring occasionally, filter though a glass filter (1G4), discard the initial 10 ml of filtrate, pass the filtrate through the same filter a second time, if necessary, to obtain a clear filtrate. Place 15 ml of the filtrate in a evaporation dish, previously dried and weighed, heat carefully on a water bath not to produce any burn, and evaporate to dryness. Dry the residue at 105• •for 1 hour and weigh accurately. Separately, perform blank test for correction.

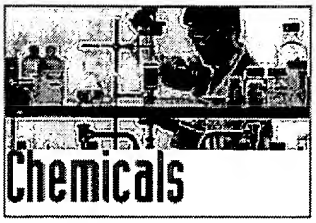
(3) Heavy metals Not more than 10 μg/g as Pb (2.0 g, Method 2, Control Solution Lead Standard Solution 2.0 ml).

(4) Arsenic Not more than 4.0 μg/g as As_2O_3 (0.50 g, Method 2, Apparatus B).

(5) Starch To 20 ml of the liquid obtained under Identification (1), add a few drops of iodine TS, and mix. No bluish purple or blue color develops.

Loss on drying Not more than 10.0% (105• ; 3 hours).

Ash Not more than 0.30% (about 800• ; 2 hours)



Chemicals A-Z

A B C
D E F
G H I
J K L
M N O
P Q R S
T U V
W X Y Z

Carboxymethylcellulose Sodium, Medium Viscosity, USP

Carboxymethylcellulose Sodium; Cellulose, Carboxymethyl Ether Sodium Salt; Sodium Carboxymethylcellulose

CAS: 9004-32-4

Bulk Quote Request

Ratings

Health: 1
Flammability: 1
Reactivity: 0

Available Quantities/Sizes

SKU	Size	Price	Quantity
SLC2032-12KG	12 kg / 25 lb	$1282.81	0
SLC2032-45KG	45 kg / 100 lb	$3886.20	0

ADD TO CART

† Limited Quantity
* Subject to Hazardous Material Fee

General Chemical Specifications:

Actual Viscosity of 2% Aqueous Solution @ 25°C	? cps
Sodium (Dried Basis)	6.5-9.5%
pH of a 1% Solution @ 25°C	6.5-8.5
MAXIMUM LIMITS	
Loss on Drying	10.0%
Heavy Metals	20µg/g
Organic Volatile Impurities	To pass test

Products

Aqualon is a worldwide supplier of a broad range of cellulose ethers and functional additives. These products improve the performance of building materials in a variety of construction applications.

Culminal® methylcellulose, methylhydroxyethylcellulose, methylhydroxypropylcellulose

CULMINAL products help building materials apply more easily and perform better. They provide water retention and cohesiveness to mixtures. With special modification, our CULMINAL methylcellulose derivatives can be used to control thickening, water demand, workability, sag resistance, strength and other important properties of the final product.

CULMINAL products are specialty products based on methylcellulose (MC) and its mixed ethers methylhydroxyethylcellulose (MHEC) and methylhydroxypropylcellulose (MHPC). Selecting the right chemistry depends on your application.

CULMINAL products are soluble in cold water and stable over a wide pH range. The different grades are chemically and physically optimized for adjusting and controlling specific properties of dry mortars and building products. They are available in different molecular weights, particle sizes and modifications.

For more information, go to CULMINAL Physical and Chemical Properties

Natrosol® hydroxyethylcellulose, regular and biostable grades

Our Natrosol product line consists of hydroxyethylcellulose products of differing molecular weights (viscosity levels) and particle sizes. Natrosol products are available as regular HEC and as HEC with increased biostability (Natrosol B). High viscosity Natrosol grades provide good thickening properties in aqueous systems. Low molecular weight Natrosol grades are often used as stabilizers in self-leveling compounds based on cement or gypsum. Our fine particle size materials, represented as X-grinds, such as Natrosol 250 HXR, are recommended whenever a quick dissolution is required.

Natrosol CG 453 is a special product for latex based building materials such as tile adhesives and plasters and has the unique feature of combining very effective thickening with high sag resistance.

For more information, go to NATROSOL Physical and Chemical Properties

Nexton® specialty water-soluble polymers

NEXTON specialty polymers are a family of non-ionic additives for the construction industry. Their unique chemistry provides desirable texture in cement, gypsum and latex-based products improving workability, cohesiveness and appearance of the building material with less influence on setting characteristics. As stand alone products or complements to Culminal or Natrosol cellulose ethers, their key function in a wide range of aqueous-based products is to manage the physical properties of water so that optimum rheology, stabilization and other wet, dry and cured properties are provided.

NEXTON products have been developed specifically for masonry systems – (NEXTON D- and M- types), for tape joint compounds – (NEXTON J- and IP- types), gypsum plaster – (NEXTON DG-types) and for stuccos and renders – (NEXTON CS-types). These products vary in viscosity, particle size, solubility and modification. Some of these products offer multi-functional performance, enhancing not only workability, but also entraining air.

Silipon™ air entraining agents and wetting agents

The Silipon range consists of various air-entraining agents. The main function of those products is to incorporate a predefined amount of homogeneously distributed air bubbles in building mortars. This reduces the density of the wet mortars and improves workability.

As dry mortar producers' requirements differ in terms of dissolution time, air content and size of air bubbles, Aqualon offers a wide range of air entraining agents to chose from.

Silipur™ defoamer

Silipur RE 2971 defoamer is very effective for dry mortars in which the air content should be as low as possible. This is especially valid for self leveling compounds based on cement or gypsum.

Starch Ethers

The starch ether range, consisting of different **Amylotex** and **ST** products, provided by Aqualon is recommended to fine-tune the anti-sagging properties of dry mortars such as tile cements, plasters and renders and to increase the yield and the water demand of those systems.

They lead to better workability and improved application properties of the wet mortar.

Galactasol® derivatized and unmodified guar-based galactomannans

The Galactasol line is a series of nonionic and anionic derivatives plus natural or unmodified guar gum that are very efficient viscosifiers and rheology agents for non-cementitious, water-based construction products. Galactasol solutions typically exhibit strong pseudoplastic behavior, excellent heat-stability, high salt tolerance, friction reduction and good cross-linkability. A typical application would include spray ceiling and wall textures.

Galactasol products are available in a variety of molecular weights, particle sizes and special modifications to effect its solubility.

Aqualon® sodium carboxymethylcellulose (CMC)
Blanose™ refined (CMC)

Aqualon sodium carboxymethylcellulose and Blanose refined CMC are two designations for the sodium salt of carboxymethylcellulose produced either in Aqualon's Alizay, France, or Hopewell, Virginia, facilities. Produced typically for industrial purposes to 98% minimum purity, CMC is anionic and acts as an effective thickener, rheology control agent, binder, stabilizer, film former and water retention aid. CMC's rapid cold and hot water solubility and ability to exhibit thixotropic behavior allow it to provide desirable properties in building materials requiring some texture in the finished product. Aqualon CMC is offered in several viscosity grades and three degrees of substitution.

For more information, go to BLANOSE Refined CMC Physical and Chemical Properties

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For more information, go to SELECTION GUIDE, Aqualon Water Soluble Polymers and Special Products, our brochure about Aqualon products for building materials or contact us.

Back

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carboxymethyl starch

1. *n.* [Drilling Fluids] ID: 1782

A natural starch derivative. CMS is used primarily for fluid-loss control in drilling muds, drill-in, completion and workover fluids. It is slightly anionic and can be affected by hardness and other electrolytes in a mud. CMS is similar to CMC (carboxymethylcellulose) in method of manufacture and many of its uses. The linear and branched starch polymers in natural starch react with monochloroacetic acid in alkaline solution, adding carboxymethyl groups at the OH positions by an ether linkage. By adding the carboxymethyl groups, the starch becomes more resistant to thermal degradation and bacterial attack.

See: carboxymethylcellulose, CMS, completion fluid, drill-in fluid, fluid-loss control, hydroxyethyl starch, hydroxypropyl starch, potassium mud

No subcategories.

18 listings found:

Download PDF

SE Tylose GmbH & Co. KG, former Clariant Functional Chemicals (English)
Producer of several water-soluble cellulose ether types such as methylcellulose (MC), methylhydroxyethylcellulose (MHEC), methylhydroxypropylcellulose (MHPC), hydroxyethylcellulose (HEC), hydroxyethylcarboxymethylcellulose (HECMC), pure and technical carboxymethylcellulose (CMC) and technical carboxymethylhydroxyethylcellulose (CMHEC). Trade names: Tylose, Tylopur, Tylodrill.

The Dow Chemical Company (English)
Producer of methylcellulose and hydroxypropyl methylcellulose (Methocel) as well as hydroxyethyl cellulose (Cellosize).

Hercules Inc. - Aqualon Division (English)
Producer of various cellulose derivatives such as methyl cellulose and MC derivatives, hydroxypropyl cellulose, hydroxyethyl cellulose, hydrophob modified hydroxyethyl cellulose, sodium carboxymethyl cellulose (CMC), and polyanionic cellulose (PAC).

Wolff Cellulosics GmbH & Co. KG (English, German)
Hydroxyethyl methylcellulose (HEMC) and hydroxypropyl methylcellulose (HPMC), as well as carboxymethylcellulose (Na-CMC). (Trade name: Walocel)

Shin-Etsu Chemical Co. Ltd.
Producer of several water-soluble cellulose ether types such as methylcellulose (MC), methylhydroxyethylcellulose (MHEC), methylhydroxypropylcellulose (MHPC), hydroxyethylcellulose (HEC), hydroxyethylcarboxymethylcellulose (HECMC), pure and technical carboxymethylcellulose (CMC) and technical carboxymethylhydroxyethylcellulose (CMHEC). Trade names: Tylose, Tylopur, Tylodrill, Metolose.

Jiangsu Feixiang Chemical Co., Ltd.
Manufacturer of cellulose derivatives: HEC, CMC, MC, and HPMC. (No details for HEC and CMC online available.) All cellulose ethers are manufactured by Suzhou Tianpu Chemical Co., Ltd., a joint venture of Jiangsu Feixiang, but the business (marketing, sales) is done by Jiangsu Feixiang. Located in China.

Shandong Head Co., Ltd.
Manufacturer of methylcellulose (MC), hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), ethyl cellulose (EC), and hydroxyethyl cellulose (HEC). Located in China.

Samsung Fine Chemicals Co., Ltd.
Manufacturer of methyl cellulose (MC), hydroxypropyl methylcellulose (HPMC) and hydroxyethyl methylcellulose (HEMC). Trade name: Mecellose.

Akzo Nobel Surface Chemistry AB
Manufacturer of ethylhydroxyethylcellulose (EHEC), methylethylhydroxyethylcellulose (MEHEC) and polyurethane-based associative thickeners. Trade names: Bermocoll, Bermodol.

Celanese Mexicana S.A. de C.V.
Manufacturer of MC (methylcellulose) and HPMC (hydroxypropyl methylcellulose) with viscosity range from 10 to 100.000 mPas in 2% solution.

Suzhou Tianpu Chemical Co., Ltd.
Manufacturer of cellulose ethers, such as methyl cellulose (MC), hydroxypropyl methyl cellulose (HPMC), hydroxyethyl cellulose (HEC) and carboxymethyl cellulose (CMC). The business (marketing & sales) is done by the holding company: Jiangsu Feixiang Chemical Co. Ltd. Located in China.

Demacasa, Derivados Macroquimicos S.A. de C.V.
Produces non-ionic cellulose ethers: HPMC (hydroxypropyl methyl cellulose) and MC (methyl cellulose) in different grades and viscosities. (Trade names: Demacol, Surfacel) Located in Mexico.

TaiAn RuiTai Cellulose Co., Ltd.
Manufacturer of cellulose ethers: methylcellulose (MC), hydroxypropyl methyl cellulose (HPMC), high-substituted hydroxypropyl cellulose (H-HPC), ethyl cellulose (EC), hydroxyethyl cellulose (HEC), hypromellose phthalate (HPMCP). Located in China.

Ronas Chemicals Ind. Co., Ltd.
Producer of hydroxypropyl cellulose (HPMC, viscosity grade between 5 and 75000) and hydroxyethyl cellulose (HEC, viscosity grade 6000 -50000). No details available online. Located in China.

CSC Jäklechemie GmbH & Co. KG
Distributor of cellulose ethers manufactured by Akzo Nobel (Bermocoll): ethylhydroxyethyl cellulose and methylethylhydroxyethyl cellulose. Located in Germany.

Prochem AG
Distributor of cellulose ethers (Dow Methocel) in the Swiss market: ethylcellulose, hydroxyethylcellulose, hydroxypropylmethylcellulose, methylcellulose. Located in Switzerland.

Pointner & Rothschädl Chemikalien Produktions- und Handelsgesellschaft m.b.H.
Distributes the cellulose ethers from Akzo Nobel Surface Chemistry (Bermocoll) in A, SK, CZ, and H.

Nordmann, Rassmann GmbH (NRC)
Distributor of cellulose ethers of The Dow Chemical Company (Methocel) for Germany. Located in Germany.

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